



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/026,517

12/27/2001

Pu Zhou

12013/61601

9382

23838

7590

08/16/2006

KENYON & KENYON LLP
1500 K STREET N.W.
SUITE 700
WASHINGTON, DC 20005

EXAMINER

SCHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/026,517	Applicant(s) ZHOU, PU	
	Examiner Laura C. Schell	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 13-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 3,4,9 is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11-12,29 is/are rejected.
- 7) ☒ Claim(s) 5-7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11, 12 and 29 rejected under 35 U.S.C. 102(b) as being anticipated by Jaraczewski et al. (US Patent No. 4,817,613). Jaraczewski discloses a medical catheter system (Fig. 1) comprising: a first steerable guide catheter (see abstract) having an entrance orifice (near 20), an exit orifice (near 5), and a first wall surrounding a channel linking the entrance orifice and the exit orifice, the first wall having a bendable curve memory portion (see abstract; col. 3, lines 34-35; col. 8, lines 33-37), wherein the bendable curve memory portion is bent into a predetermined shape and contains a plurality of flushing orifices (claim 13, note that the catheter is perfectly capable of delivering fluid or receiving fluid) and wherein the first wall contains a first layer, a second layer, and a third layer, each layer having a different hardness.

The three layers, as seen in Fig. 2 are (10), (12) and (16). Each layer has a different hardness, as layer (10) is disclosed as a flexible tubular layer, (12) is a metal braided layer, which is inherently a different hardness than (10), and (16) is a flexible casing, which is also inherently different hardness than (12). The first and third layers are also each a different hardness, as col. 10, lines 7-14 disclose that the hardness of the urethane used for the casing (16) can be varied, which would inherently allow the casing to be a different hardness than layer (10). Alternatively, the first wall of the catheter can have three layers which are different from the three layers described above. The three layers can each be a layer of the casing material, as described in col. 8, lines 5-20. This paragraph discloses that the casing made of at least two coats of a urethane (lines 6-7) and that subsequently one or more thicker urethane coats may be applied over that (lines 8-9). Further disclosed is that each coat of urethane that is applied can be of a different durometer (lines 16-18), which would therefore create at least three coats/layers of urethane, each of a different hardness. Furthermore, the definition of "coat", according to the online version of the Merriam-Webster dictionary, is "a *layer* of one substance covering another" {<http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=coat>}. If Applicant prefers to see another permutation of the three layers disclosed by Jaraczewski, one layer can be the braided metal layer (12), a second layer can be the 1-2 coats of urethane initially applied as the casing (16) as disclosed in col. 8, lines 6-7, and the third coat can be the additional coat(s) or urethane applied in a different durometer (col. 8, lines 8-9, 16-18).

Jaraczewski further discloses that the first wall contains a reinforcing structure (metal braid (12)) and the bendable curve memory portion comprises a curve memory material (see abstract; col. 3, lines 34-35; col. 8, lines 33-37). Jaraczewski further discloses that the inside surface of the first catheter includes a lubricious treatment (col. 1, lines 22-23; col. 4, lines 48-50). Jaraczewski further discloses that the orifices extend through at least two of the layers, as the entire catheter is made of at least three layers and therefore the holes must extend through all the layers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garibaldi (US Patent No. 6,524,303) in view of Fleming, 111 (US Patent No. 5,718,678). Garibaldi discloses a medical catheter system comprising: a first catheter (Fig. 1) having an entrance orifice (24), an exit orifice (26), a channel connecting the entrance and the exit orifice, a wall (22) surrounding the channel, the hardness of the wall surrounding the channel, when considered from an initial reference point at the entrance orifice and traveling towards the exit orifice, regardless of the orientation of the wall, decreasing in hardness in a first distinct region then increasing in hardness in a second distinct region and then decreasing in hardness again in a third distinct region, the hardness of the third region being different than the hardness of the first region.

Garibaldi discloses in col. 3, lines 46-55 that the catheter increases in flexibility from 24 to 26, which is equivalent to the catheter decreasing in hardness from 24 to 26.

Garibaldi further discloses in this paragraph that between the sections of decreasing hardness, a region of increased stiffness can be provided, thus creating the distinct pattern of decreasing hardness, increasing hardness and then decreasing hardness.

Garibaldi, however, does not disclose a second and third catheter within the first catheter. Fleming, discloses a second catheter (Fig. 4, 26) which is sized to move within the first catheter (42) as well as a third catheter (12) which moves within the second catheter. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Garibaldi with the nested catheters as taught by Fleming, in order to provide a multiply flexible catheter with several other catheters within it to deploy for various procedures.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garibaldi in view of Fleming and further in view of Lafontaine (US Patent No. 5,662,621).

Garibaldi in view of Fleming discloses the device substantially as claimed except for the second catheter having flushing orifices. Lafontaine, however, discloses a first catheter (Fig. 5, 26) with a second catheter within it (42) wherein the second catheter has flushing orifices (126). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Garibaldi in view of Fleming with the idea of using a second catheter with flushing orifices within a first catheter, as taught by Lafontaine, in order to provide a way of using a first catheter to guide the second

catheter within it to a spot and using the second catheter for flushing within the first catheter.

Allowable Subject Matter

Claims 5-7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 7/21/2006 have been fully considered but they are not persuasive. Applicant's explanation that each region has varying hardness within it was helpful in better understanding claim 1. Garibaldi discloses a catheter with regions increasing flexibility as one goes towards the tip of the catheter. However, Garibaldi further discloses that between each region of increasing flexibility, a region of increased stiffness can be inserted (col. 3, lines 54-56). Therefore this satisfies the requirements of claim 1, as starting from the first end of the catheter (Fig. 1, 23) the catheter increases in flexibility/decreases in hardness. Within the three designated regions of increasing flexibility, Garibaldi discloses that the regions increase gradually (col. 3, lines 54-56). Therefore, at the end of one region, it is decreasing in hardness, and then from the very edge of that region it can increase in hardness in a new region due to the insertion of the harder inserted member. And then from this new region, the hardness decreases gradually, wherein the new hardness is different from the hardness of the first region, as disclosed by Garibaldi.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

LCS

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons